

Final Report

Recommendations Regarding Supplemental Practice Expense Data Submitted for 2004

**Evaluation of Survey Data for:
Independent Laboratory**

**Prepared for:
Centers for Medicare and Medicaid Services
#500-95-0059 /TO#6**

**Prepared by:
Allen Dobson, Ph.D.
Lane Koenig, Ph.D.
Jonathan Siegel, M.A.**

The Lewin Group

September 23, 2003

TABLE OF CONTENTS

I. BACKGROUND.....	1
II. ASSESSMENT OF INDEPENDENT LABS DATA SUBMISSION	2
A. Evaluation of Survey	2
1. Confidentiality	2
2. Survey Instrument and Protocols.....	3
3. Survey Contractor	4
4. Level of Precision.....	4
5. Nationally Representative Survey of the Target Population of Physicians	4
B. Survey Results	5
C. Evaluation and Recommendation	6
D. Appendix.....	8

The College of American Pathologists (CAP) formally submitted practice expense data for independent laboratories for consideration in developing practice expense relative value units (RVUs) as part of the 2004 Medicare Physician Fee Schedule. The data were presented to the Centers for Medicare and Medicaid Services (CMS) through the Lewin Group. In this report, we present a summary of CMS's criteria for acceptance of supplemental practice expense data, a description and evaluation of the data submitted by the CAP, and our recommendation regarding whether CMS should accept these data for use in calculating practice expense RVUs for 2004.

I. BACKGROUND

The May 3, 2000 Interim Final Rule published in the *Federal Register* presented an initial set of criteria to be used in evaluating supplemental practice expense surveys. CMS received a number of comments from the public regarding the criteria and finalized the requirements for supplement survey data in its November 1, 2000 Final Rule. In its June 28, 2002 Interim Final Rule, CMS revised the standard relating to the level of precision. This report discusses The Lewin Group's evaluation of data submitted by the College of American Pathologists on independent labs with respect to these criteria. Based on The Lewin Group's independent assessment of the data, we include our recommendation on whether or not CMS should accept and use these data in the calculation of practice expense RVUs for 2004.

CMS has specified five criteria for evaluating supplemental survey data:

1. **Confidentiality:** Groups conducting surveys must ensure the confidentiality of the sample and not know the names of the individuals selected to be surveyed.
2. **Survey Instrument and Protocols:** Groups must conduct the survey based on the American Medical Association's Socioeconomic Monitoring System (SMS) survey instruments and protocols, including administrative, follow-up, and definitions of practice expenses and hours worked.
3. **Survey Contractor:** Groups must use a contractor that has experience surveying health care professionals, collecting financial information, and using random samples.
4. **Level of Precision:** A 90-percent confidence interval with a range of plus or minus 15 percent of the mean. Thus, the ratio of the standard error of the mean to the mean multiplied by 1.645 should be equal to or less than 0.15.
5. **Nationally Representative Survey of the Target Population of Physicians:**
 - a) **Random sample from complete nationwide listing** – Groups must draw the sample from AMA's Masterfile if possible. For non-physician groups not included in the Masterfile, a nationally representative sample of members and non-members must be developed.
 - b) **"High" response rate** – CMS has stated that it is impractical to set rigid response-rate cutoffs for acceptance of supplemental survey data. However, for consideration

of survey data, CMS has asked for detailed analyses that indicate that the sample is representative of the population surveyed.

II. ASSESSMENT OF INDEPENDENT LABS DATA SUBMISSION

The CAP has explained to the Lewin Group that independent laboratories have an organizational and ownership structure that do not allow for practice expenses to be measured through a physician-level survey. They described three features of independent laboratories that set them apart from a more typical physician services practice: 1) independent laboratories usually provide both *anatomic* pathology services (which are paid by the Medicare Physician Fee Schedule) and *clinical* pathology services (which are paid through the Medicare Laboratory Fee Schedule); 2) independent laboratories frequently are part of a corporation or are privately held companies that are not owned by pathologists; and 3) independent labs often contract with physicians working outside of the laboratory to supply the physician work component of the anatomic pathology services, which are then billed globally (professional plus technical components) by the laboratory.

As a consequence of these features, the CAP chose to conduct the survey at the laboratory level, rather than the physician level. They also asked for respondents to report only those physician hours and expenses that are associated with anatomic pathology, explicitly excluding the hours and expenses related to clinical pathology services. Additionally, respondents were explicitly prompted to include the hours and expenses associated with contracted physician services, and to allocate payments for these services to the appropriate cost category (e.g., physician salaries, medical supply, or medical equipment).

The survey methods described above were chosen by CAP after numerous consultations with The Lewin Group. We agreed with CAP that a standard physician-based survey would not provide meaningful results given the unique operational aspects of independent labs. We believe that the variations in the basic survey design used by CAP were justified and most likely necessary under the circumstances. In conversations arranged by CAP, we were told by representatives from independent laboratories that the separation of expenses and hours between anatomic and clinical pathology was straightforward, and that the allocation of hours and expenses for contracted outside pathologists was also feasible. Within the analysis below, we provide some validation checks regarding these assertions.

A. Evaluation of Survey

1. Confidentiality

The CAP obtained a complete list of the 1,313 CLIA-certified independent laboratories nationally, and attempted to survey all of them. Therefore, in a strict sense, the confidentiality of the sample was not preserved, since the CAP was aware that *all* labs would be included in the survey. However, the small population of independent laboratories nationally makes this problem largely unavoidable. CAP's decision to survey the entire population was made out of concern that any sub-sample may not yield an adequate number of eligible responses to enable

meeting data precision requirements. Furthermore, the identity of which labs ultimately responded with eligible data was not known to the CAP.

- Although the CAP survey does not meet the strict standard of confidentiality, The Lewin Group does not believe that this alone should determine the acceptability of the survey data. The lack of confidentiality was due to the relatively small number of independent labs, which required the need to survey all labs, rather than a sample, to generate a sufficient number of responses to meet the precision requirement. In addition, we worked with the CAP and carefully reviewed all correspondence with their membership about the survey.

In previous supplemental surveys, we have only required that specialty groups not see the sample. However, they may have been aware of the individual identities of physicians within the sample frame. For small specialties that do supplemental surveys, it may not always be feasible to satisfy the confidentiality requirement, because they may have to survey the specialty's entire population. Although it should be evaluated on a case-by-case basis, we do not believe that it is feasible to hold CAP or other small specialties accountable to the strict standards of the confidentiality requirement.

2. Survey Instrument and Protocols

As noted above, the CAP made a few substantial changes to the SMS survey model in developing a survey of independent labs. Surveying at the laboratory level represents a major departure from the SMS. The separation of hours and expenses for anatomic and clinical pathology functions is also an important difference. However, the Lewin Group believes that both of these changes are justifiable in light of the facts that independent laboratories are often corporately owned and usually provide a high volume of clinical pathology services, which do not generally involve physician work and are not included in the Physician Fee Schedule.

In almost all other expense and hours questions, the CAP survey adheres to the logic and language of the SMS survey. Explicit language is added to the survey instrument instructing respondents to include hours and expenses of contracted physicians. The SMS does not include such language, but this is a clarification deemed necessary by the structure of independent labs activities.

The survey asked laboratories to report physician hours in two different ways. One question asked for the *total* hours worked per week by *all* laboratory physicians in the provision of anatomic pathology services. A second question asked for the average weekly hours worked by *full-time* (greater than 20 hours per week) laboratory physicians. The latter question conforms more closely to the method used to obtain hours from the SMS, since the SMS is a physician-level survey that screens out part-time physicians. The former question was asked out of concern that physician work for laboratories was overwhelmingly provided on a part-time basis, due to the typical outside-contracting arrangements at many of these labs. If this were true, the average full-time weekly hours would not be accurate as a measure of the per-physician weekly hours overall.

The Lewin Group recommends using the weekly hours per full-time physician in the calculation of total practice (laboratory) physician hours, since this is most conformable to the methods imposed on other specialties in the SMS and other prior supplementary surveys. The responding independent laboratories reported that 10 percent of their physicians are part-time (i.e., less than 20 hours of clinical care per week). Though the SMS does not contain data to serve as a comparison, two prior supplemental surveys submitted to CMS showed 12 percent of optometrists as part-time, and 5 percent of medical oncologists. In our view, the fraction part-time reported by independent labs does not justify making a special exception to the methodology applied to all other specialties.

The Lewin Group believes that CAP's survey contractor followed the same protocols used by the SMS contractor. A letter and practice expense worksheet were reviewed by the Lewin Group and sent prior to attempting to contact the potential respondents by phone. The contractor conducted follow-up phone calls and had a toll-free number for respondents to call so that they could complete the survey at their convenience.

- The Lewin Group is satisfied that the CAP survey meets the standards of survey instrument and protocols required by CMS.

3. Survey Contractor

The CAP hired a survey contractor with prior experience conducting supplemental practice expense surveys. This contractor conducted the survey independently and submitted the data directly to the Lewin Group.

- The Lewin Group is satisfied that the CAP survey contractor meets the standards required by CMS.

4. Level of Precision

The Lewin Group compiled the results from the CAP survey and computed a measure of the level of precision for total practice expenses per hour. As described by the CMS regulations, the level of precision is measured by the standard error of the mean divided by the mean multiplied by 1.645. This measure should not exceed 15 percent. The relevant CAP survey estimate is:

Level of Precision for Total Practice Expense per Hour for 2001 = 12.9%

- The level of precision for Total Practice Expense per Hour satisfy the *Level of Precision* requirement specified in the June 28, 2002 Interim Final Rule.

5. Nationally Representative Survey of the Target Population of Physicians

a. Random sample from complete nationwide listing

The CAP survey attempted to obtain responses from all 1,313 CLIA-certified labs nationwide, based on a listing provided by CMS.

b. Response rate

The CAP survey achieved a low response rate. In total, we calculated that approximately 14% (N=90) of potentially eligible respondents completed the survey questions on practice expenses and hours worked. Such a low response rate raises questions regarding the representativeness of the results. To address this issue, we examined how PE per hour varied by size of practice, and examined the geographic dispersion of respondents.

The outcomes of the analyses are shown in Appendix A of this report. We summarize the findings below:

- The difference between small practices (2 pathologists or fewer) and larger practices in mean total practice expense per hour was large: ranging from \$199 per hour for labs with 1 pathologist to \$151 per hour for labs with 5 to 7 pathologists. Such disparities in PE per hour might be influential on mean values if the labs that responding to the survey are not representative of the size distribution in the population. Based on an analysis of the number of personnel at CLIA-certified labs in the *Provider of Service* database, we believe that the responding sample is adequately representative of the size distribution in the population, and the differences across practice size are not leading to erroneous means.
- Respondents appear to be geographically diverse. The overall average practice expense GPCI for the 111 respondents with practice expense data (prior to the exclusions) was 0.961. Although this is less than the average for all 1313 independent labs (0.989), the difference is not large.
- Our comparisons of the responding sample to the national population of independent labs *do not suggest the existence of strong non-response bias.*

B. Survey Results

In the Table 1, we report mean practice expense per hour values for anatomic pathology services provided at independent laboratories, weighted by practice size.

**Table 1: 2001 Practice Expenses Per Hour of Physician Clinical Work
Anatomic Pathology Services at Independent Laboratories
(Weighted by Number of Practice Physicians)**

	Estimated Mean N=90	Standard Error N=90	Precision [1.645 × Mean/SE] N=90
<i>Direct PE per hour</i>			
Clinical Payroll	\$75.63	10.10	0.220
Medical Equipment	\$7.88	1.22	0.255
Medical Supplies	\$17.70	2.30	0.214
<i>Indirect PE per hour</i>			
Office Expense	\$17.03	3.32	0.320
Clerical Payroll	\$22.98	2.87	0.205
Other Expense	\$19.27	3.08	0.263
<i>Total PE per hour</i>	\$160.50	12.57	0.129

C. Evaluation and Recommendation

During the CAP survey planning process, the Lewin Group had two major concerns over the ability of the CAP survey to collect accurate data for hours and expenses. First, we were uncertain that respondents would be able to accurately report the hours and category-allocated expenses associated with external physicians contracted to perform anatomic pathology services billed by the laboratory. Second, we were unsure that expenses associated with anatomic pathology would be separable from clinical pathology.

To assess these two issues, we considered both the distribution of expenses by practice expense category and the average compensation per employed physician and non-physician staff. The details of these analyses are shown in Appendix A. Our conclusions from the analyses are:

- The distribution of practice expenses of independent labs is heavily weighted toward non-physician clinical staff costs (47% of total practice expense), as compared with the expense category distribution from the SMS all-physician average (22%).
- Further examination reveals that reported annual payroll costs per clinical employee at independent labs (\$53,788), are consistent with survey data on national average compensation costs for medical and clinical laboratory technologists. Also, the average ratio of clinical staff to physicians (2.6 to 1) is similar to the ratio of clinical staff time to physician time, for procedures at independent labs, implied by other CMS data.

- Average compensation per physician (\$207,667) is similar to prior SMS survey data on pathologist income (\$208,000 in 1998).
- Our concern that the contracted expenses for compensating external pathologists would be incorrectly allocated to a practice expense category does not appear to be a problem in the data. Relative to one another, the five expense categories other than clinical staff have a distribution similar to that of other physician specialties.

Recommendation Regarding Acceptance

The value of total practice expenses in anatomic pathology per physician hour at independent labs was measured at \$160.50 for 2001 in the CAP survey. This amount is substantially higher than the all-physician average practice expense per hour, and is at the upper end of the distribution of practice expenses per hour across all specialties. But this fact alone cannot justify a rejection of the data, and no prior survey has collected any practice expenses information for independent labs, so we are left with no direct comparisons. The high figure does mandate an important role for the analysis verifying the validity and plausibility of the data. In addition to assessing the data's conformity to standard CMS requirements, the Lewin Group examined the data in several ways to address each concern we had over the data's validity.

The Lewin Group is satisfied that the CAP survey, and the data submitted from that survey, meet formal CMS requirements for supplemental practice expense data. We are also satisfied that the data hold up to the additional scrutiny we imposed on it by examining the distribution of expenditures across practice expense category, implied annual compensation levels, and staffing ratios. In our view, the relatively high total practice expense per hour appears realistic, and is likely explained by the relatively intensive role of non-physician technicians in the provision of anatomic pathology services.

- The Lewin Group recommends that CMS accept the practice expense per hour values reported in Table 1 (Appendix A), and use these values for calculation of 2004 practice expense RVUs for the Medicare Physician Fee Schedule.

D. Appendix

Sample

The CAP survey attempted to obtain responses from all 1,313 CLIA-certified labs nationwide, based on a listing provided by CMS. A sample was not used.

Response Rates

The contractor obtained 212 completed surveys from independent labs. In calculating practice expenses per hour, we excluded cases with any individual practice expense items missing (111 records eliminated), cases with missing data on average weekly hours of clinical care or annual weeks not practicing (8 records eliminated), and cases where reported practice expenses were zero or invalid (3 records eliminated). These edits are consistent with prior evaluations of practice expense data, and reduce the sample size to 90 observations.

We calculated response rates in three different ways. In each, we exclude (from the 1,313 CLIA-certified labs on the list) 213 labs screened out on eligibility grounds. Those screened out include labs without anatomic pathology services, labs no longer in operation, and labs not in operation for the full year 2001.

We first calculated the response rate by taking the ratio of observations in our sample (90) to the total sample excluding screened-out cases (1100):

$$\text{Initial Response Rate: } 90 / 1100 = 8.2\%$$

This calculation of the response rate may be misleading, however, because it includes all 888 cases where a potential respondent failed to complete the screener section of the survey. These non-contacted cases included labs for which a contact was not available, labs with disconnected or incorrect telephone numbers, and labs that refused to participate in the survey. Presumably, a proportion of these individuals would have been found to be ineligible had they completed the screener section of the survey. By taking the ratio of screened-out cases (213) to all contacted cases (425), we estimate that 445 of the 888 cases would have been screened out had they been contacted. As a result, the sample pool would only be 655, and the revised response rate is:

$$\text{Adjusted Response Rate 1: } 90 / 655 = 13.7\%$$

We made another calculation of the response rate by first eliminating those cases that had bad or incorrect contact information (325). There is reason to expect that these cases would be more likely than other non-contacted cases to be screened out if data had been collected. Recalculating our “Adjusted Response Rate 1” with these observations removed gives:

$$\text{Adjusted Response Rate 2: } 90 / 493 = 18.3\%$$

Methodology

Construction of Weights

Any weighting used for the purpose of calculating of practice expense per hour should conform closely to the methods used for SMS data. Because the CAP survey is a practice-level survey, starting from a practice-level list, there is naturally a higher representation of small practices than would occur in a randomly drawn physician list. For example, consider a 10-physician practice versus a solo physician practice. In a physician-level survey, the odds of the 10-physician practice being surveyed are ten times the odds of the solo practice being surveyed. However, in a practice-level survey, the odds of each practice being surveyed are equal.

To make the practice expense per hour results from data collected by the practice-level survey most conformable to methods used with SMS data, we have weighted the data by the number of physicians in each practice. For purposes of comparison, we have also included the results of the unweighted practice-level data.

The list used by CAP was of all labs CLIA-certified in anatomic pathology. Thus, there was no need for additional weighting by membership status or location.

Edits

The contractor obtained 212 completed surveys from independent labs. In calculating practice expenses per hour, we excluded cases with any individual practice expense items missing (111 records eliminated), cases with missing data on average weekly hours of clinical care or annual weeks not practicing (8 records eliminated), and cases where reported practice expenses were zero or invalid (3 records eliminated). These edits are in accordance with prior evaluations of practice expense data, and reduce the sample size to 90 observations.

Results

In the Table 1, we report mean practice expense per hour values for anatomic pathology services provided at independent laboratories, weighted by practice size. In Table 2, we show the unweighted results.

**Table 2: 2001 Practice Expenses Per Hour of Physician Clinical Work
Anatomic Pathology Services at Independent Laboratories
(Unweighted)**

	Estimated Mean N=90	Standard Error N=90	Precision [1.645 × Mean/SE] N=90
<i>Direct PE per hour</i>			
Clinical Payroll	\$54.90	6.14	0.184
Medical Equipment	\$6.05	0.98	0.267
Medical Supplies	\$24.53	3.16	0.212
<i>Indirect PE per hour</i>			
Office Expense	\$23.98	4.25	0.292
Clerical Payroll	\$31.56	3.35	0.175
Other Expense	\$24.68	3.16	0.211
<i>Total PE per hour</i>	\$165.70	11.68	0.116

Evaluating the accuracy of the reported data

The Lewin Group had two major concerns regarding the ability of the CAP survey to produce accurate data for hours and expenses. First, we were uncertain that respondents would be able to accurately report the hours and category-allocated expenses associated with external physicians contracted to perform anatomic pathology services billed by the laboratory. Second, we were unsure that expenses associated with anatomic pathology would be separable from clinical pathology. In several discussion with CAP and representatives from independent labs, prior to the survey, they assured us that responding labs would be able to provide this information accurately. We attempted to verify this fact as much as possible, given the data collected.

Table 3 shows the distribution of practice expenses by category for independent labs, as based on the CAP survey. Also shown is the distribution of practice expenses for the all-physician average, based on the 1998 SMS survey.

Table 3: Percent Distribution of Practice Expenses, by Expense Category

	Share of Total PE	
	Independent Labs ^a	All-Physician Average ^b
Clinical Payroll	47%	22%
Medical Equipment	5%	5%
Medical Supplies	11%	11%
Office Expense	11%	28%
Clerical Payroll	14%	22%
Other Expense	12%	16%

a/ Source: CAP, 2001 Survey of Independent Labs.

b/ Source: AMA, 1998 Socioeconomic Monitoring System (SMS).

The distribution of practice expenses of independent labs is heavily weighted toward non-physician clinical staff payroll, which is a notable difference from the expense category distribution of the SMS all-physician average. Aside from that major difference, the other expense categories follow roughly the same relative relationship to one another as with the other physician specialties.

If compensation for contracted physician care was incorrectly being included in practice expense categories, we expect it would end up in the “other expense” category, since each of the other categories is specific enough to exclude such contract expenses. The fact that this category is 12 percent of total practice expenses (as compared to a 16 percent physician average) suggests that physician compensation was correctly excluded from practice expense.

The larger-than-usual expense for non-physician clinical employees could be a result of either higher levels of employment of such staff, or high compensation levels for that staff (or both). We considered both of these possibilities in turn. Table 4 shows independent labs annual compensation costs per physician, clinical employee, and clerical employee, as well as the ratio of non-physician staff to physicians.

Table 4: Average Compensation and Staff Ratios in Independent Labs

	Average (N=78)
Physician Compensation	\$207,667
Non-Physician Clinical Employee Payroll	\$53,788
Non-Physician Clerical Employee Payroll	\$33,513
Non-Physician Clinical Employees per Physician	2.6
Non-Physician Clerical Employees per Physician	2.0

The Bureau of Labor Statistics' 2001 *National Occupational Employment and Wage Estimates* shows a national average annual wage of \$43,060 for medical and clinical laboratory technologists. This does not include non-wage compensation costs, which tend to average 25 to 30 percent across all occupations nationally, according to separate BLS data. Thus the non-physician clinical payroll expenses at independent labs do not appear unusually high on a per-employee basis.

Also we note that the compensation of physicians seems plausible, which suggests a proper category allocation of contracted expenses. Based on a small sample, the American Medical Association reported an average pathology income of approximately \$208,000 in 1998 (According to the *Physician Socioeconomic Statistics: 2000-2000 Edition*).

To evaluate whether the reported ratio of clinical staff to physicians is realistic, we referred to CMS data used elsewhere in the practice expense methodology. Using 1997-2001 procedure utilization data for independent labs, physician time per procedure, and clinical staff time inputs per procedure, we calculated the aggregate ratio of clinical staff time to physician time for independent labs. The result was 3.0 to 1, which is sufficiently close to the 2.6 to 1 staffing ratio reported in the survey.

The Lewin Group also spoke to one medical director of an independent lab about the role of clinical staff in typical anatomic pathology procedures. The physician described a typical operation, where it is often the case that two or more clinical staff – some of whom are highly skilled – are involved in the pre-preparation of specimens. These staff are generally dedicated to anatomic pathology work, and not usually involved with clinical pathology procedures.

Evaluating the Representativeness of the Sample

To examine the representativeness of the responding sample of independent labs, we examined how PE per hour varied by size of practice, and examined the geographic dispersion of respondents.

Practice Size

Table 5 shows practice expenses by size of lab.

**Table 5: 2001 Practice Expenses Per Hour by Lab Size,
Anatomic Pathology Services at Independent Laboratories**

Size of Lab Number of Pathologists	Number of Labs	Total PE per Hour	Standard Error
1	18	\$199.10	29.57
2	18	\$194.39	29.67
3-4	20	\$151.13	18.95
5-7	15	\$151.04	25.08
8+	19	\$158.85	30.66

The variation in mean total practice expense per hour based on the number of pathologists in the lab is large. This does raise a concern if the labs responding to the survey differ in size distribution from the labs not responding. There is no source of information providing the distribution nationally of independent labs by number of physicians, but we were able to use information from the CMS Provider of Service (POS) files showing the number of personnel at each site satisfying CLIA requirements for performing “non-waived” (i.e., moderate or high complexity) testing. Although this will not correspond directly to the number of physicians or clinical staff performing anatomic pathology, we do expect the number of personnel to be *proportional* to the number of physicians working for the lab. Table 6 compares the distribution of personnel across labs, for the respondent and non-respondent groups of independent labs from the 1,262 in the population for which we have this information.

Table 6: Distribution of CLIA-Certified Labs, by Number of Personnel Authorized for “Non-Waived” Testing

	Respondents		Non-Respondents		Population Total	
	N	Percent	N	Percent	N	Percent
0 to 2	42	39%	407	35%	449	36%
3 to 5	27	25%	269	23%	296	23%
6 to 10	15	14%	187	16%	202	16%
11 to 20	11	10%	81	7%	92	7%
21+	14	13%	209	18%	223	18%
Total	109	100%	1153	100%	1262	100%

These data show no large differences in size distribution between respondents and the total population of labs. The largest category (21+ personnel) is the only category with more than a three percentage point difference. If the two largest categories are combined, the respondent group with 11 or more personnel are 23 percent of all responding labs, while in the population they are 25 percent of all labs.

Geographic Distribution

Respondents appear to be geographically diverse. Responding labs hail from 39 states, covering all geographic regions nationally. The overall average practice expense GPCI for the 111 respondents with practice expense data (prior to the exclusions) was 0.961. Although this is less than the average for all 1313 independent labs (0.989), the difference is not large.